

# EXHIBIT F



LEXSEE 933 P.2D 298, 303

**ALPHA EDWARDS, Personal Representative of the Estate of John T. Edwards, Deceased, Plaintiff/Appellant, v. BASEL PHARMACEUTICALS, a division of Ciba-Geigy Corporation, Defendant/Appellee.**

**No. 87,192**

**SUPREME COURT OF OKLAHOMA**

**933 P.2d 298; 1997 Okla. LEXIS 20; 68 O.B.A.J. 794; 57 A.L.R.5th 793; CCH Prod. Liab. Rep. P14,894**

**March 4, 1997, Filed**

**DISPOSITION:**  [\*\*1] CERTIFIED QUESTION ANSWERED.

**COUNSEL:** Rex K. Travis, Margaret E. Travis, Oklahoma City, Oklahoma, Attorneys for Appellant.

James E. Weger, C. Michael Copeland, JONES, GIVENS, GOTCHER & BOGAN, P.C., Tulsa, Oklahoma, Attorneys for Appellee.

**JUDGES:** KAUGER, C.J., SUMMERS, V.C.J., HODGES, LAVENDER, SIMMS, HARGRAVE, JJ., Concur, OPALA, J., Concurs in part and Dissents in part, WATT, J., Dissents

**OPINION BY:** SUMMERS

**OPINION**

[\*299] CERTIFIED QUESTION FROM THE UNITED STATES COURT OF APPEALS FOR THE 10TH CIRCUIT

Summers, J.:

Widow claims her husband's death was due to his use of a prescribed pharmaceutical product. Her theory of liability against the manufacturer is that the manufacturer failed to [\*\*2] adequately warn her husband of the effects of overdose. The manufacturer responds that it fully warned the prescribing physician of the pertinent risks, and further complied with Food and Drug Administration requirements for warning the ultimate user. The case is in the United States Court of Appeals for the Tenth Circuit, which has certified to us the following as an unsettled question of state law:

Under Oklahoma law, what determines the scope or extent of the prescription drug manufacturer's duty to warn the consumer when FDA recognition of the need for direct warnings has undercut application of the learned intermediary rule? More specifically, what is the effect of the manufacturer's compliance with the very FDA requirements invoking this exception to the rule?

Boiled down, our answer is that compliance with FDA warning requirements does not necessarily satisfy the manufacturer's common law duty to warn the consumer.

The facts provided in the Order of Certification are these. Alpha Edwards brought a wrongful death action for the death of her husband. He died of a nicotine-induced heart attack as a result of smoking cigarettes while wearing two Habitrol nicotine patches. [\*\*3] Habitrol is manufactured by Basel Pharmaceuticals. Plaintiff's theory of liability was that the warnings given in conjunction with the Habitrol patches were inadequate to warn her husband of the fatal risk associated with smoking and overuse of the product. A relatively thorough warning was given to physicians providing the Habitrol patch, but the insert provided for the user did not mention the possibility of a fatal or cardiac related reaction to a nicotine overdose, cautioning that an "overdose might cause you to faint."

The pamphlet provided to Dr. Howard and other physicians prescribing the patch said:

Prostration, hypotension and respiratory failure may ensue with large overdoses. Lethal doses produce convulsions quickly and death follows as a result of peripheral or central respiratory paralysis or, less frequently, cardiac failure.

With regard to the manufacturer's warning directed by the FDA for the ultimate user, the certifying judge said this:

Although the operative administrative regulation, directive, or stipulation was never produced, defendant expressly admitted that the patient insert it included with its [\*300] product had been "mandated . . . by the FDA."

She [\*\*4] further noted the Defendant's unchallenged assertion that the user's insert had been "approved by the FDA" (her emphasis). So for the purposes of our answer to the question we take as fact "the manufacturer's compliance with the very FDA requirements" of warning to the consumer.

#### THE LEARNED INTERMEDIARY DOCTRINE

Basel contends that the "learned intermediary doctrine" bars liability, because the prescribing physicians were given complete warnings regarding the use of the patches. Basel concedes that consumer warnings were required by the FDA, but argues that by complying with those FDA warning requirements the case again is controlled by the learned intermediary doctrine, with its attendant shield affording protection to the manufacturer. Mrs. Edwards disagrees, stating that the warnings given to her late husband were inadequate, regardless of whether FDA requirements were met.

Our products liability law generally requires a manufacturer to warn consumers of danger associated with the use of its product to the extent the manufacturer knew or should have known of the danger. *Kirkland v. General Motors*, 521 P.2d 1353 (Okla. 1974). Certain products, prescription drugs among [\*\*5] them, are incapable of being made safe, but are of benefit to the public despite the risk. Their beneficial dissemination depends on adequate warnings, and the law regarding such products appears at Comment k of the Restatement (Second) of Torts, § 402A. <sup>1</sup> *Tansy v. Dacomed Corp.*, 890 P.2d 881, 885 (Okla. 1994). The user must be adequately warned. *Id* at 886.

1 Comment k in relevant part, states:

Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.

[\*\*6] There is, however, an exception known as the "learned intermediary doctrine", which Oklahoma has recognized as applicable in prescription drug cases, *McKee v. Moore*, 648 P.2d 21, 24 (Okla. 1982) <sup>2</sup>, and prosthetic implant cases, *Tansy v. Dacomed Corp.*, *supra*. The doctrine operates as an exception to the manufacturer's duty to warn the ultimate consumer, and shields manufacturers of prescription drugs from liability if the manufacturer adequately warns the prescribing physicians of the dangers of the drug. *McKee*, at 24. The reasoning behind this rule is that the doctor acts as a learned intermediary between the patient and the prescription drug manufacturer by assessing the medical risks in light of the patient's needs. *Cunningham v. Pfizer*, 532 P.2d 1377, 1381 (Okla. 1975).

2 *McKee v. Moore* was actually an intrauterine contraceptive device (IUD) case, but its language makes clear that the doctrine is applicable in prescription drug cases in Oklahoma based on failure to warn. 648 P.2d at 24.

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Where a product is available only on prescription or through the services of a physician, the physician acts as a 'learned intermediary' between the manufacturer or seller and the patient. It is his duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and to exercise independent judgment, taking into account his knowledge of the patient as well as the product. The patient is expected to and, it can be presumed, does place primary reliance upon that judgment. The physician decides what facts should be told to the patient. Thus, if the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent [\*301] learning, in the best interest of the patient.

*Wooderson v. Ortho Pharmaceutical Corp.*, 235 Kan. 387, 681 P.2d 1038, 1052 (Kan. 1984), *cert. denied*, 469 U.S. 965, 83 L. Ed. 2d 301, 105 S. Ct. 365 (1984). The doctrine extends to prescription drugs because, unlike over the counter medications, [\*\*8] the patient may obtain the drug only through a physician's prescription, and the use of prescription drugs is generally monitored by a physician. *Lukaszewicz v. Ortho Pharmaceutical Corp.*, 510 F. Supp. 961, 962 (E.D. Wis. 1981). The learned intermediary doctrine has been held applicable to prescription nicotine gum, because there was a sufficient relationship established between doctor and patient. *Tracy v. Merrell Dow Pharmaceuticals*, 58 Ohio St. 3d 147, 569 N.E.2d 875 (Ohio 1990).

#### EXCEPTIONS TO THE LEARNED INTERMEDIARY DOCTRINE

Two exceptions have been recognized which operate to remove the manufacturer from behind the shield of the learned intermediary doctrine. The first involves mass immunizations. *Cunningham*, at 1381; *Allison v. Merck & Co., Inc.*, 110 Nev. 762, 878 P.2d 948 (Nev. 1994). Mass immunizations fall outside the contemplated realm of the learned intermediary doctrine because there may be no physician-patient relationship, and the drug is not administered as a prescription drug. *See Percival v. American Cyanamid Co.*, 689 F. Supp. 1060, 1061 (W.D.Okla. 1987). Under these conditions individualized attention may not be given by medical personnel in assessing the needs of the patient. [\*\*9] The only warnings the patient may receive are those from the manufacturer. Oklahoma has adopted this exception. *Cunningham*, at 1381.

The second exception, which has been adopted by several jurisdictions including Oklahoma, arises when the Food and Drug Administration mandates that a warning be given directly to the consumer. *McKee v. Moore*, *supra*. By this exception several states have held that the learned intermediary doctrine itself does not protect the manufacturer. *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 475 N.E.2d 65 (Mass. 1985), *cert. denied*, 474 U.S. 920, 88 L. Ed. 2d 258, 106 S. Ct. 250 (1985); *Odgers v. Ortho Pharmaceutical Corp.*, 609 F. Supp. 867 (E.D.Mich. 1985); *Spychala v. G.D.Searle Co.*, 705 F. Supp. 1024 (D.N.J. 1988); *Lukaszewicz v. Ortho Pharmaceutical Corp.*, 510 F. Supp. 961 (E.D.Wis. 1981). *But see Lacy v. G.D.Searle & Co.*, 567 A.2d 398 (Del. 1989)(refused to adopt the exception); *Kociemba v. G.D.Searle & Co.*, 680 F. Supp. 1293 (D.Minn. 1988); *Goodson v. Searle Laboratories*, 471 F. Supp. 546 (D.Conn. 1978). Most of the cases adopting this exception have dealt with contraceptives and the FDA's extensive regulation of contraceptive drugs and devices. *See* [\*\*10] 21 C.F.R. § 310.501 and § 310.502 (requirements for patient and physician warnings with regard to intrauterine devices and birth control pills). However, courts have not limited the exception to this arena alone.

We see no reason that this second exception should not apply to nicotine patches available by prescription. When direct warnings to the user of a prescription drug have been mandated by a safety regulation promulgated for the protection of the user, an exception to the learned intermediary doctrine exists, and failure on the part of the manufacturer to warn the consumer can render the drug unreasonably dangerous. According to the material certified by the Federal Court, the FDA has found a need to require that prescriptions for nicotine patches be accompanied by warnings to the ultimate consumer as well as to the physician, as is required in the distribution of oral contraceptives and intrauterine devices.

#### DOES FDA COMPLIANCE REINSTATE THE LEARNED INTERMEDIARY DOCTRINE?

The question then becomes whether the manufacturer has fulfilled its legal obligation once the warnings are approved by the FDA and transmitted to the user. Basel contends that because it complied with [\*\*11] FDA requirements it had no further duty to warn Mr. Edwards. Jurisdictions split on their answer to this question. In *MacDonald*, 475 N.E.2d at 70, 71, the court held that compliance with FDA regulation did not reinstate the learned intermediary doctrine so as to [\*302] absolve the manufacturer's liability for inadequate warnings. *See also McEwen v. Ortho Pharmaceutical Corp.*, 270 Ore. 375, 528 P.2d 522 (Ore.1974)(warnings to physicians were not sufficient even though they met FDA standards).

Some courts have held compliance with FDA requirements is sufficient to bring a case back within the learned intermediary rule. In *Spychala v. G.D.Searle & Co.*, 705 F. Supp. at 1033, the

federal district court held that the FDA exception "undercuts if not abrogates the learned intermediary rule and should be narrowly construed." Likewise, in *Lacy v. G.D.Searle & Co.*, 567 A.2d at 401, 402, the Delaware court found that compliance with FDA regulations and approval of the patient brochure by the FDA satisfied the requirement of a direct patient warning.

The case of *Medtronic Inc v. Lohr*, 518 U.S. 470, 135 L. Ed. 2d 700, 116 S. Ct. 2240 (1996) is helpful in coming to a decision. In *Medtronic*, the United States **Supreme** Court [\*\*12] held that the FDA's regulation of medical devices does not preclude state tort liability. The Court was faced with the question of whether FDA procedures and regulations under the Medical Device Act, 21 U.S.C. Section 360(k), preempted state law liability. Plaintiff brought suit after her pacemaker failed, alleging among other things, that the warnings were inadequate. The manufacturer claimed that federal law preempted any state cause of action.

The Court first noted that it has long been within the realm of the individual states, under their police powers, to protect the health and safety of their citizens. Although the federal government has taken an increasingly active role in this arena since the enactment of the Food and Drug Act of 1906, common law actions are not automatically preempted.

The Supreme Court continued its preemption analysis by pointing out the two critical presumptions governing this issue: (1) that a state's police power is not superseded by federal law unless there is a clear and manifest expression to the contrary and (2) that the intent of Congress is the ultimate touchstone. *Id.* Relying on these presumptions, the Court turned to the plaintiff's claims [\*\*13] of inadequate warnings accompanying the pacemaker, and held that the adequacy of warnings is a question of state law. Plaintiff's action based on inadequate warning was not precluded by the pervasive federal regulation in the area of medical devices.<sup>3</sup>

3 Cases which have found federal preemption of state law claims have done so on the basis of express language in federal statutes or regulations. In *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 120 L. Ed. 2d 407, 112 S. Ct. 2608 (1992), the Supreme Court held that the federal statutes preempted state law claims because the language in the statute specifically stated that no requirement or prohibition based on state law shall be imposed. Likewise, in *Lewis v. American Cyanamid Co.*, 294 N.J. Super. 53, 682 A.2d 724 (N.J. 1996), the New Jersey Superior Court held that specific language in the Federal Insecticide, Fungicide and Rodenticide Act preempted state claims that the warning labels were inadequate. See also *Bokis v. American Medical Systems, Inc.* 875 F. Supp. 748 (W.D. Okla. 1995)(Medical Device Act preempted state law claims.); *Meyer v. International Playtex Inc.*, 724 F. Supp. 288 (D. N.J. 1988)(Medical Device Act preempted state tort action for inadequate warning since FDA requirements were met).

[\*\*14] It has long been the concern of this state to protect the health and safety of its citizens. The Supreme Court has recognized that state concern is warranted and permitted. *Medtronic, supra*. It is the widely held view that the FDA sets **minimum** standards for drug manufacturers as to design and warnings. *Kociemba*, at 1298. We conclude that compliance with these minimum standards does not necessarily complete the manufacturer's duty. *Accord Mazur v. Merck & Co.*, 742 F. Supp. 239, 247 (E.D.Pa. 1990)(FDA approved warnings regarding a vaccination did not preclude state tort liability for inadequate warnings); *Patten v. Lederle Laboratories*, 655 F. Supp. 745 (D. Utah 1987)(compliance with FDA requirements does not bar state law claims for manufacturer design flaws or inadequate warnings). The common law duty to warn is controlled by state law. *Kociemba*,

at 1298-99; *Odgers v. Ortho Pharmaceutical Corp.* 609 F. Supp. 867 (E.D. Mich. 1985); *Graham v. Wyeth Laboratories*, 666 F. Supp. 1483 (D.Kan. 1987); *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 475 N.E.2d 65 (Mass. 1985). Even the [\*303] FDA agrees, as noted by the FDA Commissioner who observed that civil tort liability [\*\*15] for failure to warn is governed by state law. *MacDonald*, at 70, citing 43 Fed. Reg. 4214 (1978).

Although the common law duty we today recognize is to a large degree coextensive with the regulatory duties imposed by the FDA, we are persuaded that, in instances where a trier of fact could reasonably conclude that a manufacturer's compliance with FDA labeling requirements or guidelines did not adequately apprise [prescription drug] users of inherent risks, the manufacturer should not be shielded from liability by such compliance.

*MacDonald*, at 70 <sup>4</sup>. It may be that in certain instances compliance with FDA warning procedures will satisfy all state law requirements. But although compliance with FDA standards may prove an effective starting ground, it is not necessarily conclusive. The adequacy of warnings is determined by state law. Our result could improve the safety of prescription drugs by requiring that both standards are met. *Mazur*, at 248.

4 See also *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652 (1st Cir. 1981); *McEwen v. Ortho Pharmaceutical Corp.*, 270 Ore. 375, 528 P.2d 522 (Ore. 1974).

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Oklahoma requires that the manufacturer warn of dangers which are foreseeable and known to the manufacturer. *Duane v. Oklahoma Gas & Electric Co.*, 833 P.2d 284, (Okla. 1992). Those warnings must be adequate to inform the user of the dangers associated with the product's use. See *Tansy*, 890 P.2d at 886; *Hutchins v. Silicone Specialties*, 881 P.2d 64 (Okla. 1993). The manufacturer is not, however, required to warn of obvious dangers. *Grover v. Superior Welding, Inc.*, 893 P.2d 500 (Okla. 1995).

In the present case it appears the manufacturer clearly had knowledge of the dangers associated with the Habitrol patch; it furnished detailed warnings to the prescribing physicians. However, as to the warnings the late Mr. Edwards received in his Habitrol insert, state products liability law must be applied to determine their adequacy.

## CONCLUSION

We hold that when the FDA requires warnings be given directly to the patient with a prescribed drug, an exception to the "learned intermediary doctrine" has occurred, and the manufacturer is not automatically shielded from liability by properly warning the prescribing physician. When this happens the manufacturer's duty to warn the [\*\*17] consumer is not necessarily satisfied by compliance with FDA minimum warning requirements. The required warnings must not be misleading, and must be adequate to explain to the user the possible dangers associated with the product. Whether that duty has been satisfied is governed by the common law of the state, not the regulations of the FDA, and necessarily implicates a fact-finding process, something beyond our assignment in response to this certified question.

Question Answered.

KAUGER, C.J., SUMMERS, V.C.J., HODGES, LAVENDER, SIMMS,

HARGRAVE, JJ. - Concur

OPALA, J., - Concurs in part and Dissents in part

WATT, J., - Dissents

**CONCUR BY:** SIMMS; OPALA (In Part)

**CONCUR**

SIMMS, J. CONCURRING:

I concur in the majority opinion and respectfully observe that pre-emption is not an issue in this case.

**DISSENT BY:** OPALA (In Part)

**DISSENT**

**OPALA, J.**, dissenting in part.

The court *pronounces* that whenever the federal Food and Drug Administration's [FDA] safety regulations require warnings to be given directly to a user of prescription drugs, (a) an exception is to be recognized to the "learned-intermediary doctrine"<sup>1</sup> and (b) [\*304] a manufacturer's failure to give the required warning may render the [\*18] drug "unreasonably dangerous". Today's opinion *teaches* that (a) the FDA sets *minimum* standards for drug manufacturers' design and warnings, and (b) although, in some circumstances, compliance with FDA regulations may satisfy *all* state-law requirements, *adherence to FDA regulations* does not generally discharge the manufacturer's duty. Resting its pronouncement on the rationale that state common-law norms control the standards that govern the duty to warn [where liability is *not* pre-empted by federal law], the court concludes that (a) the manufacturer is *not* automatically shielded from liability by imparting *a warning to the physician*, and (b) a manufacturer's common-law duty to *warn directly the consumer-patient* is *not* necessarily met by compliance with the FDA minimum warning requirements. The common-law duty to warn, the court *explains*, requires that the consumer be *adequately informed of the dangers* associated with the product's use.

1 The *learned intermediary rule* "holds that manufacturers of prescription drugs discharge their duty of care to patients by warning the health-care providers who prescribe and use the drugs to treat them." Reporters' Note, Comment d, § 8, RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY (Proposed Final Draft (Preliminary Version) October 18, 1996). The American Law Institute (ALI) has undertaken the process of drafting the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY. James A. Henderson, Professor, Cornell Law School, and Aaron D. Twerski, Professor, Brooklyn Law School, have been selected as reporters for the project.

[\*19] I would *declare* today that Oklahoma's common law follows the proposed (but not yet adopted) text of the Restatement (Third) of Torts: Products Liability<sup>2</sup> and its pertinent comments. Inasmuch as in cases that are *not* federally pre-empted the proposed Restatement leaves each jurisdiction free to shape the outer limit of liability, *I would announce* that because compliance with a

nonpre-emptive federally required warning constitutes *no more than evidence* of the manufacturer's reasonable conduct, it may *not* by itself be regarded as a liability-defeating defense.

**2 Comment e, § 7, RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY (Proposed Final Draft (Preliminary Version) October 18, 1996).**

*Several drafts of the third Restatement have been released: a preliminary draft in April 1993; Council Draft No. 1 in September 1993, Council Draft No. 2, was released September 2, 1994. The most recent version (and the one discussed here), Proposed Final Draft (Preliminary Version) was released October 18, 1996.*

[\*\*20] I strongly *disagree* with the concuree who regards federal pre-emption as unrelated to the certified question before us. Some FDA rules are deemed pre-emptive.<sup>3</sup> When pre-emption stands declared, there will be no room left for applying state law to gauge a federally prescribed warning's adequacy.

**3 See Medtronic, Inc. v. Lohr, 518 U.S. 470, 116 S. Ct. 2240, 2253-2254, 135 L. Ed. 2d 700 (1996).**

**I**

**FEDERAL PRE-EMPTION, PARTIAL OR TOTAL, MUST INDEED  
BE ADDRESSED IN DEALING WITH LAW THAT IS TO GOVERN IN  
THE SCENARIO DESCRIBED BY THE CERTIFYING COURT**

Federal pre-emption *is fairly comprised* within the certified question before us. This is so because the claim's scenario calls for a dichotomous division of its legal treatment. In one subclass there would be (a) cases affected by pre-emption (and hence totally or partially excluded from state-law impact) and in another (b) those that are unaffected by pre-emption and hence governed *exclusively* by state law.

In the first category, [\*\*21] a manufacturer's showing of compliance with the FDA requirement that warning be given directly to the patient may take the case completely out of the state-law reach.<sup>4</sup>

**4 Comment b, § 8, RESTATEMENT (THIRD), supra note 1, states in part:**

" \* \* \* *The rules imposing liability on a manufacturer for inadequate warning or defective design of prescription drugs and medical devices assume that compliance with a governmental regulatory standard has not preempted the imposition of tort liability.* Where such pre-emption is found as a matter of law, liability cannot attach when the manufacturer has complied with the applicable regulatory standard. See § 7. The doctrine of pre-emption based on supremacy of federal law should be distinguished from the proposition that compliance with statutory and regulatory standards satisfies the state's requirement for product safety." (Emphasis supplied.)

Comment e, § 8, *RESTATEMENT (THIRD)*, *supra* note 1, states in part:

" \* \* \* Where *the content of the warnings is mandated or approved by a governmental agency* regulation and a court finds that compliance with such regulation *federally preempts tort liability, then no liability under this Section can attach. . . .*" (Emphasis supplied.)

[\*\*22] [\*305] Comment e, Restatement (Third) of Torts: Products Liability § 7, <sup>5</sup> states in pertinent part:

5 Comment e, § 7, *RESTATEMENT (THIRD)*, *supra* note 2.

". . . In federal pre-emption the court decides as a matter of federal law that the relevant federal statute or regulation reflects, expressly or impliedly, the intent of Congress to displace state law, including state tort law, with the federal statute or regulation. The question of preemption is thus a question of federal law and a determination that there is preemption nullifies otherwise operational state law.

The complex set of rules and standards for resolving questions of federal preemption are beyond the scope of this Restatement. However, when federal preemption is found, the legal effect is clear. Federal preemption replaces the tort law of all states with a uniform body of federal law regulating the relevant area of product safety. Federal preemption takes one or more of three different forms. *First*, a federal statute may by its terms expressly [\*\*23] preempt state law. *Second*, a federal statute which does not expressly preempt state law may otherwise reveal the intent of Congress to occupy the regulatory field. *Third*, even in the absence of an express preemption clause or congressional intent to occupy the field completely, a federal law preempts all state laws with which it is in actual conflict. An actual conflict exists when the application of state law frustrates the accomplishment of congressional objectives, as when it is impossible to comply with both the state and federal law and when the state law interferes with the accomplishment of the full purposes of Congress. Judicial deference to federal product safety statutes or regulations occurs not because the court concludes that compliance with the statute or regulation shows the product to be nondefective; the issue of defectiveness under state law is never reached. Rather, the court defers because, when a federal statute or regulation is preemptive, the Constitution mandates federal supremacy." (Emphasis added.)

There are some FDA rules that federal jurisprudence treats as absolutely pre-emptive. <sup>6</sup> When this form of pre-emption stands declared, all state law is [\*\*24] displaced. None may be interposed.

6 The U.S. Constitution, art. VI, cl. 2, makes the laws of the United States "the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." When Congress acts within the scope of its constitutionally delegated authority, the supremacy clause empowers Congress "to pre-empt state laws to the extent it is believed that such action is necessary to achieve its purposes." *City of New York v. Federal Communications Comm'n*, 486 U.S. 57, 63, 108 S. Ct. 1637, 1642, 100 L. Ed. 2d 48 (1988). Likewise, Congress may delegate regulatory authority to an administrative agency, and when the agency acts within the scope of that authority, it may pre-empt and "render unenforceable state or local laws that are otherwise not inconsistent with federal law." *Id.*, quoting from *Louisiana Pub. Serv. Comm'n v. Federal Communications Comm'n*, 476 U.S. 355, 369, 106 S. Ct. 1890, 1898-99, 90 L. Ed. 2d 369 (1986); *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153-54, 102 S. Ct. 3014, 3022-23, 73 L. Ed. 2d 664 (1982). Pre-emption is a matter of

congressional intent and may occur in four distinct instances: (1) by express statutory language; (2) by a pervasive regulatory scheme which infers the presence of congressional intent that the federal regulation did not need supplemental state-law provisions; (3) when an actual conflict between state and federal laws makes it impossible to comply with both; or (4) where the objectives and purposes of Congress are thwarted by state law. *City of New York, supra*, 486 U.S. at 64, 108 S. Ct. at 1642; *Fidelity Federal Sav. & Loan Ass'n, supra*, 458 U.S. at 153, 102 S. Ct. at 3022. *See also* Lewis v. Sac and Fox Tribe of Oklahoma Housing Authority, Okl., 896 P.2d 503, 510-511 (1995); Todd v. Frank's Tong Service, Inc., Okl., 784 P.2d 47, 49 (1989); Missouri-Kansas-Texas R. Co. v. State, Okl., 712 P.2d 40, 46-47 (1985).

[\*\*25] II

### **THE OUTER LIMIT OF LIABILITY IN CLAIMS THAT ARE NOT FEDERALLY PRE-EMPTED**

According to § 8(b), Restatement (Third) of Torts: Products Liability, a drug or medical device is defective if at the time of sale or other distribution it (1) *contains a manufacturing defect*, (2) *is not "reasonably safe due [\*306] to defective design"*, or (3) *is not "reasonably safe due to inadequate instruction or warnings"*.<sup>7</sup> Warnings should be given directly to patients when the manufacturer is aware that no medical provider will be in a position to play the role of the learned intermediary.<sup>8</sup> *The Restatement has left to developing case law to resolve whether other exceptions to the learned intermediary rule should be recognized.*<sup>9</sup> *I accede to this view.*

7 Section 8(d), *RESTATEMENT (THIRD)*, *supra* note 1, states:

(d) A prescription drug or medical device is not reasonably safe because of inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

(1) prescribing and other health care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or

(2) the patient when the manufacturer knew or had reason to know that no health care provider would be in a position to reduce the risks of harm in accordance with the instructions or warnings.

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8 The Reporters' Note, Comment e (direct warning to patients), § 8, *RESTATEMENT (THIRD)*, *supra* note 1, explains that many of the cases in this category deal with vaccines administered *en masse* at public health clinics. *See, e.g.,* Givens v. Lederle, 556 F.2d 1341 (5th Cir. 1977)(applying Florida law); Reyes v. Wyeth Laboratories., 498 F.2d 1264 (5th Cir. 1974)(applying Texas law); Brazzell v. United States, 788 F.2d 1352 (8th Cir. 1986)(swine flu vaccine); Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir. 1968). *See also* Allison v. Merck and Co., Inc., 110 Nev. 762, 878 P.2d 948, 959 (Nev. 1994), where the court states that "although a manufacturer may decide to assign its duty to warn of the unsafeness of its product [a vaccine] to others [in the case, i.e., the Center for Disease Control], a manufacturer cannot be relieved of ultimate responsibility for assuring that its unsafe product is dispensed with a proper warning."

9 Comment e, § 8, *RESTATEMENT (THIRD)*, *supra* note 1; Reporters' Note, Comment e, § 8, *RESTATEMENT (THIRD)*, *supra* note 1.

Section [\*\*27] 7(b) of the Restatement<sup>10</sup> addresses the question of *what effect, if any*, should be given to a manufacturer's compliance with a *nonpre-emptive* federal product safety statute or regulation *upon the contested issue* of product defectiveness.<sup>11</sup> Subsection (b) follows the traditional view that most product safety statutes or regulations generally set only minimum standards.<sup>12</sup> *The proposed Restatement takes no position upon the parameters [\*\*307] of liability in cases where state law governs and there has been compliance with the prescribed nonpre-emptive warnings directly to the patient.*<sup>13</sup> Though not yet adopted, the current draft appears to rest on sound principles. I would hence hold that today's jurisprudence fills the gap left open by the proposed Restatement.

10 Section 7 (b), *RESTATEMENT (THIRD)*, *supra* note 2, states:

"In connection with liability for defective design or inadequate instructions or warnings:

\* \* \*

(b) a product's compliance with an applicable product safety statute or regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, *but such compliance does not preclude as a matter of law a finding of product defect.*" (Emphasis added.)

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11 Comment e, § 7, *RESTATEMENT (THIRD)*, *supra* note 2, states in pertinent part:

" \* \* \* An important distinction must be drawn between the subject addressed in Subsection (b) [*supra* note 10] and the matter of federal preemption of state products liability law. Subsection (b) addresses the question of whether and to what extent, as a matter of state tort law, compliance with product safety statutes or regulations affects liability for product defectiveness. When a court concludes that a defendant is not liable by reason of having complied with safety design or warnings statutes or regulation, it is deciding that the product in question is not defective as a matter of law of that state. *The safety statute or regulation may be a federal provision, but the decision to give it determinative effect is a state law determination [in nonpre-emptive cases]. . . .*

Accordingly, Subsection (b) addresses the effects of compliance with a federal statute or regulation found to be nonpreemptive. It addresses the question, *under state law*, of the effect that compliance with product safety statutes or regulations -- federal or state -- should have on the issue of product defectiveness. *Subsection (b) reflects the traditional view that the standards set by most product safety statutes or regulations generally are only minimum standards. Thus, most product safety statutes or regulations establish a floor of safety below which product sellers fall only at their peril, but they leave open the question of whether a higher standard of product safety should be applied. This is the general rule, applicable in most cases.* \* \* \* " (Emphasis supplied.)

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12 See Comment e, § 7, *RESTATEMENT (THIRD)*, *supra* note 11. See also Reporters' Note, Comment e, § 7, *RESTATEMENT (THIRD)*, *supra* note 2, which states that "the overwhelming majority of jurisdictions hold that [generally] compliance with product safety regulation is *relevant and admissible . . .* but is not necessarily controlling." (Emphasis supplied.) The Reporters' Note cites *O'Gilvie v. International Playtex, Inc.*, 821 F.2d 1438 (10th Cir. 1987); *Sours v. General Motors Corp.*, 717 F.2d 1511, 1517 (6th Cir. 1983); *Foyle v. Lederle Laboratories*, 674 F. Supp. 530, 533 (E.D.N.C. 1987); *Brooks v. Beech Aircraft Corp.*, 120 N.M.

372, 902 P.2d 54, 63 (N.Mex. 1995); Washington State Physicians Ins. Exchange & Assoc. v. Fisons Corp., 122 Wash. 2d 299, 858 P.2d 1054 (Wash. 1993). The Reporters' Note *observes* that "in holding compliance with product safety regulations is nonconclusive, courts often indicate that such safety regulations are merely 'minimum standards.'" For this notion, the Reporters' Note *cites* Feldman v. Lederle Laboratories, 132 N.J. 339, 625 A.2d 1066 (N.J. 1993); Plenger v. Alza Corp., 11 Cal. App. 4th 349, 362 (1992); Stevens v. Parke, Davis & Co., 9 Cal. 3d 51, 507 P.2d 653, 107 Cal. Rptr. 45 (Cal. 1973), and *states* that "although the great majority of courts find conformance with product safety regulations nonconclusive on the issue of defectiveness, *courts occasionally recognize special circumstances in which the opposite conclusion is justified.*" (Emphasis supplied.) Among the cases cited are Lorenz v. Celotex Corp., 896 F.2d 148 (5th Cir. 1990); Ramirez v. Plough, Inc., 6 Cal. 4th 539, 863 P.2d 167, 176 (Cal. 1993); Dentson v. Eddins & Lee Bus Sales, 491 So. 2d 942, 944 (Ala. 1986).

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13 See Comment e, § 7, *RESTATEMENT (THIRD)*, *supra* note 11.

Since the proposed Restatement leaves each jurisdiction free to shape the outer limit of liability, I would declare that compliance with a prescribed nonpre-emptive direct warning serves as proof of a manufacturer's reasonable conduct, but cannot ordinarily be invoked as a liability-defeating defense. To overcome the proof of compliance with the prescribed direct warning the plaintiff need not show more than that the warning (a) did not by itself make the product reasonably safe for use by the intended consumer or (b) was not adequate under the circumstances. The parties in litigation would thus stand free to contest whether (a) the product itself and/or (either or both) (b) the prescribed manner of its application under the warnings that were given may be regarded as reasonably safe.

The task of analyzing today's answer for its application to this case must be deferred to the certifying court.<sup>14</sup> If that court should decide that FDA regulations in suit are indeed pre-emptive, no state law is invocable. If they are not [\*\*31] to be deemed pre-emptive, our answers will apply.

14 See, e.g., Shebestor v. Triple Crown Insurers, 974 F.2d 135, 137 (10th Cir. 1992).

## SUMMARY

I would adopt today as the common law of Oklahoma the pertinent text of the proposed Restatement (Third) with the relevant comments. Because the proposed Restatement leaves Oklahoma free to shape the outer limit of liability to be borne by a manufacturer who has given the patient the prescribed nonpre-emptive direct warning, I would treat its compliance with that regulatory or statutory requirement as no more than proof of the manufacturer's reasonable conduct.

In the scenario submitted by the certifying court, *the effect of federal pre-emption must be taken into account*. If the pertinent regulation is to be accorded pre-emptive force -- a question beyond state law's control -- a manufacturer's showing of compliance with the FDA requirement that warning be given directly to the patient *will* take the case entirely out of the reach of Oklahoma's [\*\*32] common-law norms.